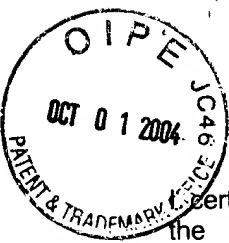


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I certify that on 9/28/04, which is the date I am signing this certificate, this correspondence and all attachments mentioned are being deposited in the United States Postal Service as first class in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Craig A. Slavin

PATENT

Applicant: Whayne et al.

Serial No.: 09/507,613

Filing Date: 02/21/00

Title: Catheter Distal Assembly

With Pull Wires

Group Art Unit: 3763

Examiner: Rodriguez

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF REPLY BRIEF

Sir:

In response to the Examiner's Answer dated August 25, 2004, transmitted herewith in triplicate is the Reply Brief.

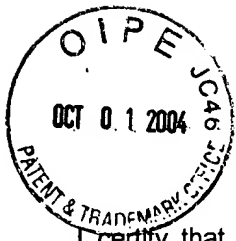
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

9/28/04
Date

Respectfully submitted,

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(310) 563-1458, (310) 563-1460 (Facsimile)



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Alexandria, VA 22313-1450

**Attention: Board of Patent
Appeals and Interferences**

REPLY BRIEF

Sir:

In response to the Examiner's Answer dated August 25, 2004, please enter and consider the following:

I. Grouping of the Claims

On page 4 of the Appeal Brief filed on May 11, 2004 (“the May 11, 2004 Appeal Brief”), applicant stated that claims 10-21 stand or fall together and claims 22-37 stand or fall together. Applicant notes that this statement included a typographical error and should have read “claims 10-13 and 15-21 stand or fall together” because claim 14 has not been rejected and, instead, has been objected to. To that end, and in accordance with 37 C.F.R. § 1.192(c)(7), applicant argued the claims 22-37 are patentably distinct from **claims 10-13 and 15-21** on pages 23 and 24 of the May 11, 2004 Appeal Brief.

The statement concerning the grouping of the claims in Section 7 of the Examiner’s Answer appears to indicate that claim 14 stands or falls with claims 10-13 and 15-21. Given that claim 14 was not rejected, applicant respectfully requests that Section 7 be corrected to read that claims 10-13 and 15-21 stand or fall together and that claims 22-37 stand or fall together.

II. Issues Associated With The Priority Claim of the Present Application

Claims 10-12, 15-23 and 27-37 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,071,279 to Whayne (“the Whayne ‘279 patent”). The Whayne ‘279 patent is based on an application that was filed on **December 19, 1996**. The present application is a continuation of U.S. application Serial No. 08/961,374, which is itself a continuation-in-part of U.S. application Serial No. 08/769,856, filed **December 19, 1996** (“the Yang ‘856 priority application”).¹

Applicant argued on pages 7-9 of the May 11, 2004 Appeal Brief that, to the extent that the Whayne ‘279 patent anticipates claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e):

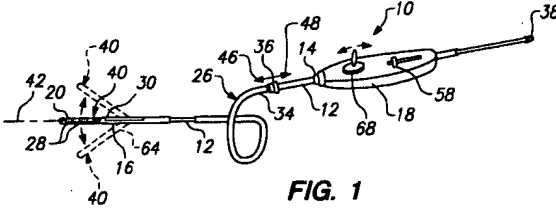
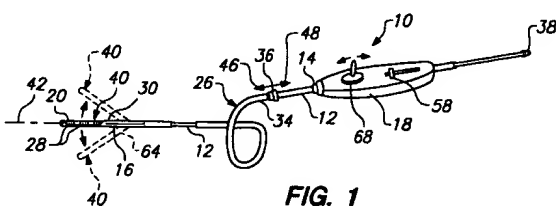
(1) the Examiner failed to show that claims 10-12, 15-23 and 27-37 are not entitled to the December 19, 1996 filing date of the Yang ‘856 priority application;

¹ U.S. application Serial No. 08/961,374 issued as U.S. Patent No. 6,203,525 and the Yang ‘856 priority application issued as U.S. Patent No. 6,332,880.

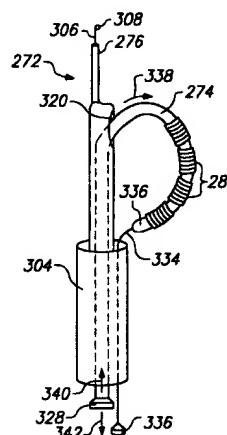
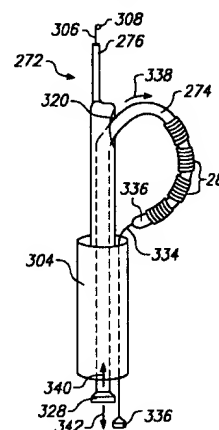
(2) absent such a showing the effective filing dates of claims 10-12, 15-23 and 27-37 and the Whayne '279 patent are the same; and

(3) if the effective filing dates are the same, then the Whayne '279 patent is not prior art with respect to claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e).²

The May 11, 2004 Appeal Brief also noted that the disclosures of the Whayne '279 patent and the Yang '856 priority application are essentially identical and that the portions of the Whayne '279 patent identified in the outstanding Office Action as corresponding to the claimed subject matter are **completely identical** to the corresponding portions of the Yang '856 priority application. The relevant portions of the Whayne '279 patent and the Yang '856 priority application are reproduced in the table below.

<p>Figure 1 of the Whayne '279 Patent</p>  <p>FIG. 1</p>	<p>Figure 1 (formal version) of the Yang '856 priority application</p>  <p>FIG. 1</p>
<p>Column 11, lines 45-57 of the Whayne '279 Patent</p> <p>Additional tissue contact forces can be generated by mounting a bendable spring 64 in the distal end 16 of the catheter tube (see FIG. 2A). One or more steering wires 66 are bonded (e.g., soldered, spot welded, etc.) to the bendable spring 64 extend back to a steering mechanism 68 in the handle 18 (see FIG. 1). Details of steering mechanisms that can be used for this purpose are shown in Lundquist and Thompson U.S. Pat. No. 5,254,088, which is incorporated into this Specification by reference. Operation of the steering mechanism 68 pulls on the steering wires 66 to apply bending forces to the spring 64. Bending of the spring 64 bends the distal end 16 of the catheter tube 12, as shown in phantom lines in FIG. 1.</p>	<p>Page 24, line 25 to page 25, line 5 of the Yang '856 priority application</p> <p>Additional tissue contact forces can be generated by mounting a bendable spring 64 in the distal end 16 of the catheter tube (see Fig. 2A). One or more steering wires 66 are bonded (e.g., soldered, spot welded, etc.) to the bendable spring 64 extend back to a steering mechanism 68 in the handle 18 (see Fig. 1). Details of steering mechanisms that can be used for this purpose are shown in Lundquist and Thompson U.S. Pat. No. 5,254,088, which is incorporated into this Specification by reference. Operation of the steering mechanism 68 pulls on the steering wires 66 to apply bending forces to the spring 64. Bending of the spring 64 bends the distal end 16 of the catheter tube 12, as shown in phantom lines in Fig. 1.</p>

² It is, however, applicant's position that the rejection of claims 10-12, 15-23 and 27-37 under 35 U.S.C. 102(e) is improper because the claims are not anticipated by the Whayne '279 patent.

Figure 53 of the Whayne '279 Patent**FIG. 53****Figure 53 (formal version) of the Yang '856 priority application****FIG. 53**

Column 27, line 66 to column 28, line 15 of the Whayne '279 Patent

FIG. 53 shows an embodiment of the structure 272, which like FIG. 51, allows movement of the operative branch 274 through a slot 320. Unlike the embodiment in FIG. 51, the embodiment shown in FIG. 53 includes a pull wire 334 attached to the distal end 336 of the operative branch 274. The pull wire 334 passes through the exterior sheath 304 or through the catheter tube 12 (previously described) to an accessible stop 336. Advancing the operative branch 274 forward (arrow 338) through the slot 320, while holding the pull wire 334 stationary, bends the operative branch 274 into a loop, in much the same manner previously described in connection with the FIG. 15A embodiment. Pulling on the wire 334 (arrow 342) reduces the amount of exposed length beyond the distal end of the sheath 304. By advancing the catheter tube (arrow 340), the radius of curvature of the looped operative branch 274 can be adjusted, in much the same way previously shown in the FIG. 17A embodiment.

Page 61, line 28 to page 62, line 12 of the Yang '856 priority application

Fig. 53 shows an embodiment of the structure 272, which like Fig. 51, allows movement of the operative branch 274 through a slot 320. Unlike the embodiment in FIG. 51, the embodiment shown in Fig. 53 includes a pull wire 334 attached to the distal end 336 of the operative branch 274. The pull wire 334 passes through the exterior sheath 304 or through the catheter tube 12 (previously described) to an accessible stop 336. Advancing the operative branch 274 forward (arrow 338) through the slot 320, while holding the pull wire 334 stationary, bends the operative branch 274 into a loop, in much the same manner previously described in connection with the Fig. 15A embodiment. Pulling on the wire 334 (arrow 342) reduces the amount of exposed length beyond the distal end of the sheath 304. By advancing the catheter tube (arrow 340), the radius of curvature of the looped operative branch 274 can be adjusted, in much the same way previously shown in the Fig. 17A embodiment.

In view of the identical disclosure, applicant noted in the May 11, 2004 Appeal Brief that the Office Action has taken two seemingly contradictory positions, i.e. that the Whayne '279 patent anticipates claims 10-12, 15-23 and 27-37 because it discloses each and every element of each of the claims, and that the essentially identical Yang '856 priority application does not support the subject matter defined by claims 10-12, 15-23 and 27-37. To that end, applicant also argued that:

(1) the mere fact that the present application is a continuation of an application that is itself a continuation-in-part of the Yang '856 priority application does not necessarily preclude the claims of the present application from being supported by the Yang '856 priority application; and

(2) the Office Action did not even assert, let alone prove, that any of claims 10-12, 15-23 and 27-37 fail to meet the conditions outlined in MPEP § 201.11 for receiving the benefit of the Yang '856 priority application when the claims are interpreted in the manner set forth in the Office Action.

In response to the arguments above, Section 11, paragraph 10 of the Examiner's Answer states that "[t]he claimed subject matter in the instant application" is not disclosed in the Yang '856 priority application.³ This statement is particularly noteworthy because the portions of the Whayne '279 patent identified in the outstanding Office Action as corresponding to the claimed subject matter are *identical* to the corresponding portions of the Yang '856 priority application. Given the identity of disclosure, the Examiner's Answer has apparently taken the position that the claimed subject matter is *not disclosed* in the Whayne '279 patent. For this reason alone, the rejection under 35 U.S.C. § 102(e) is improper and should be reversed.

III. Claim Interpretation Issues Associated With Claims 10-13 and 15-21

In the May 11, 2004 Appeal Brief, applicant argued that the Office Action's interpretation of the phrase "strain relief element" is unreasonable because it is inconsistent with the specification of the present application and it is inconsistent with the meaning ascribed to the term "strain relief" by those of skill in the art. [May 11, 2004 Appeal Brief at pages 9-21.] Applicant further argued that, when a reasonable interpretation of the phrase "strain relief element" is applied, the rejection of claims 10-12 and 15-21 under 35 U.S.C. § 102(e) is improper and should be reversed, as is the rejection of claim 13 under 35 U.S.C. § 103. [May 11, 2004 Appeal Brief at pages 21-23.] The response to these arguments in the Examiner's Answer raises a variety of

³ The Examiner's Answer actually referred to U.S. Patent No. 6,332,880, which issued from the Yang '856 priority application.

issues. In the interest of simplicity, applicant will simply address them in the order that they first appear.

In Section 11, paragraph 7, the Examiner's Answer states that "[i]t is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim." *Citations omitted*. Applicant did not argue that limitations from the specification should be read into the claims. To the contrary, the applicant correctly argued that the claims should not be interpreted in a manner that is entirely inconsistent with the present specification and the Whayne '279 patent. [May 11, 2004 Appeal Brief at pages 10-12.]

In Section 11, paragraph 8, the Examiner's Answer states that "[c]laim construction begins with the language of the claims ... In construing patent claims, there is 'a heavy [sic] 'heavy presumption' that a claim term carries its ordinary and customary meaning,' ... namely its meaning 'amongst artisans of ordinary skill in the relevant art at the time of the invention.'" *Citations omitted*.⁴ Applicant agrees with this statement and, to that end, cited five analogous patents in the May 11, 2004 Appeal Brief which showed that the Examiner's definition of the term "strain relief element" is in conflict with its meaning amongst artisans of ordinary skill in the catheter art. [May 11, 2004 Appeal Brief at pages 12-15.] The Examiner's Answer, on the other hand, failed to produce any "skilled artisan" evidence whatsoever to support the unreasonable interpretation of the claims in the Office Action.

In Section 11, paragraph 9, the Examiner's Answer cites a variety of Federal Circuit cases that appear to have little or no relevance to the actual issues at hand. Accordingly, applicant has no reply.

In Section 11, paragraphs 11 and 13, the Examiner's Answer appears to be attempting to respond to applicant's argument that it is improper to cobble together a

⁴ This paragraph of the Examiner's Answer also states that "[d]ictionaries and treatises may also assist the courts' ... '[j]udges. . . may. . . rely on dictionary definitions' to construe claim terms." *Citations omitted*. The issues associated with dictionaries and the Examiner's improper usage thereof are discussed below with respect to Section 11, paragraphs 11 and 13.

definition of the term “strain relief element” from the separate definitions of the terms “strain” and “relief” in a general-usage dictionary that clearly conflicts with teachings of the present specification and five analogous patents. [May 11, 2004 Appeal Brief at pages 15-17.] Unfortunately, the Examiner’s Answer continues to mischaracterize the “definitions” aspect of *In re Morris*, 44 USPQ 1023, 1027-28 (Fed. Cir. 1997), in that the “definitions” referred to in *In re Morris* were definitions in ***applicant’s specification, not in a general usage dictionary***. The Examiner’s Answer also failed to address the issues raised by *AFG Industries Inc. v. Cardinal IG Co.*, 57 USPQ2d 1776, 1783 (Fed. Cir. 2001) (“This court has repeatedly cautioned against using non-scientific dictionaries for defining technical words ... A general definition is secondary to the specific meaning of a technical term as it is used and understood in a particular technical field”), which applicant brought to the Examiner’s attention.

Instead of responding to applicant’s arguments, Section 11, paragraph 11 of the Examiner’s Answer merely reiterated that “it would not be proper for the examiner to give words of the claim special meaning when no such special meaning has been defined by the applicant in the written description.” Notwithstanding the fact that applicant is seeking to have the phrase “strain relief element” interpreted in a manner that is consistent with the understanding of the skilled artisan, and is not attempting to obtain a “special meaning,” the May 11, 2004 Appeal Brief spent approximately one and one-half pages (see pages 19 and 20) explaining why the Examiner’s “special meaning” requirement is improper. The Examiner’s Answer did not address a single one of applicant’s arguments concerning the “special meaning” requirement.

The Examiner’s Answer did, however, continue to assert that the separate definitions of the terms “strain” and “relief” in the *American Heritage Dictionary of the English Language, Third Edition* (1992) supported the interpretation of the term “strain relief element” in the Office Action. [Examiner’s Answer at Section 11, paragraph 13.] Applicant respectfully submits that this assertion is categorically incorrect. In addition to ignoring the Federal Circuit decision in *AFG Industries Inc.*, the Examiner’s Answer also failed to take into account the more recent Federal Circuit decision in *Vanderlande Industries Nederland BV v. International Trade Commission*, 70 USPQ2d 1696, 1704

(Fed. Cir. 2004) (“a general-usage dictionary cannot overcome credible art-specific evidence of the meaning or lack of meaning of a claim term.”) Applicant has provided five patents from the catheter art to show what those of skill in the art would understand “strain relief element” to mean, while the Examiner has provided nothing other than the separate general-usage dictionary definitions of the terms “strain” and “relief.” It should also be noted the *Vanderlande* decision criticized the parsing of a two-word term (i.e. “glide surface”) in an attempt to derive meaning of the two-word term from general-usage dictionary definitions. *Id.* at 1704.

In Section 11, paragraph 13, the Examiner’s Answer re-iterated the contention that the “‘strain relief element’ is a descriptive word and does not impart any specific structure (in the claims) since has not being [sic] well described structurally and functionally in the claims with respect and in combination to [sic] the other elements.” *Emphasis in original.* Applicant respectfully notes that “strain relief element” is not a descriptive word, it is a phrase. More importantly, it is a phrase that applicant has shown to have a specific meaning in the art. Thus, although the claims are not limited to any particular style of “strain relief element,” the claims do in fact require a “strain relief element” and further require that the “strain relief element” be part of a handle and be secured to a control element that extends along the exterior surface of a catheter body. [See Claim 10.]

In Section 11, paragraph 12, the Examiner’s Answer includes a discussion of 35 U.S.C. § 112, sixth paragraph, and a suggestion that applicant employ means-plus-function claims. The suggestion is respectfully noted. However, as applicant is clearly entitled to the claims in their current state, there is no reason to convert them to means-plus-function format.

In Section 11, paragraph 14, the Examiner’s Answer appears to indicate that the fact that five analogous patents use the phrase “strain relief” in a particular way is irrelevant because the present application does not include a corresponding definition of

the phrase "strain relief."⁵ More specifically, the Examiner's Answer states that "the fact that in the abovementioned patents, a particular element has been named "strain relief", does not mean that the name does impart any structural weight in the claims unless it is well defined structurally in both the claims and in the disclosure." Here again, the Examiner's Answer is categorically incorrect. There is simply no requirement that an applicant, who uses a term in the same manner that those of skill in the art use it, define the term "structurally in both the claims and in the disclosure." Instead, as noted on page 10 of the May 11, 2004 Appeal Brief, the PTO's interpretation of the claims must be "consistent with the specification," "consistent with the one that those skilled in the art would reach" and "should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art." *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999).

As the interpretation of the claims 10-12 and 15-21 is inconsistent with the specification and is inconsistent with the one that those skilled in the art would reach (as evidenced by the conflict with the five patents from the catheter art), the rejection under 35 U.S.C. § 102(e) is improper and should be reversed.

IV. Claims 22-37

On pages 24 and 25 of the May 11, 2004 Appeal Brief, applicant argued that the rejection of claims 22, 23 and 27-37 under 35 U.S.C. § 102(e) and the rejection of claims 24-26 under 35 U.S.C. § 103 are both improper. The Examiner's Answer did not address any of applicant's arguments concerning claims 22-37.

⁵ Applicant has assumed for the purposes of this brief that the reference to only four of the five patents and the use of the term "*non*-analogous" in this portion of the Examiner's Answer are merely typographical errors.

V. Concluding Remarks

As applicant has shown above and in the May 11, 2004 Appeal Brief, the rejections of claims 10-13 and 15-37 are improper and should be reversed.

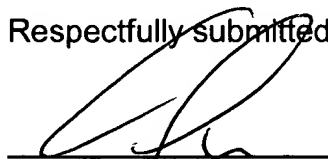
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Respectfully submitted,



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